

REMARKS

Claims 68, 73-77, 86, 94, 95 and 105-118 are pending in the application, claims 105-115 being newly added herein. Claims 1-9, 12-18, 22-29, 31-40, 58, 59, 67, 70-72, 78-85, 87-90, 92, 93, and 96-104 are canceled herein without prejudice to applicant's right to resubmit those claims in a subsequently filed divisional application. Claims 10, 11, 19, 20, 21, 30, 41-57, and 60-66, 69 and 91 were previously canceled. Claims 68, 73, 109, 110, 112, 113, and 115-118 are the only independent claims.

The Examiner has made the previously issued Restriction Requirement final. Accordingly, non-elected claims 1-9, 12-18, 22-29, 31-40, 58, 59, 67, 70-72, 78-85, 87-90, 92, 93, and 96-104 are canceled herein. Applicant reserves the right to pursue the canceled claims in one or more subsequently filed divisional applications.

Claims Rejections - 35 U.S.C. §§ 102 and 103

Claims 68, 73, 74, 76 and 94 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over the article "Non-Coherent Near Infrared Radiation Protects Normal Human Dermal Fibroblasts from Solar Ultraviolet Toxicity" by Menezes et al., Institute de Recherche sur la Peru, 1998 ("Menezes").

Claims 68, 73, 77, and 86 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Menezes article in view of a summer beach vacation.

Claims 75 and 94 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Menezes article.

The Invention Applicant's invention pertains in principal part to a *prophylactic* method of applying electromagnetic radiation to skin surfaces to reduce, if not eliminate, the incidence or likelihood that those skin surfaces will suffer visible cosmetic damage particularly including radiation dermatitis and poikiloderma respectively caused by exposure to a source of Xray or ultraviolet radiation (see page 1, second paragraph, of applicant's disclosure). As set forth in

well-known and widely respected dermatology texts, including Fitzpatrick's *Dermatology & General Medicine* (6th Ed., 2003), Mark Lebwohl's *Treatment of Skin Disease*, 2nd Ed., 2006, and Morris Leider's *A Dermatology Dictionary*, 1968, radiation dermatitis and poikiloderma are characterized by darkened skin color (hyperpigmentation), lightened skin color (hypopigmentation), redness (erythema), itching (pruritus), swelling (edema), thinning (atrophy), scar tissue (fibrosis), fine blood vessel prominence, wrinkling and dry skin. These skin conditions arise from adverse effects of radiation on melanin (hyperpigmentation, hypopigmentation), blood vessels (erythema and blood vessel prominence), keratinocytes or epidermal cells (itching, dry skin), and collagen (atrophy, scar tissue, wrinkling, swelling). Applicant's invention in part directs light pulses specifically at these targets and is therefore designed to reduce the respective skin conditions. (See especially Paragraphs 0020 and 0165 of the published application.) As described in applicant's disclosure, light scattering the application of light pulses in accordance with applicant's invention also achieves a healing response through light scattering.

Pursuant to applicant's method, electromagnetic radiation is applied to a skin surface increasing the local temperature in skin structures including blood vessel cell walls and keratinocytes in the skin to stimulate a healing response and a release of growth factors and other tissue substances, without permanently damaging the skin structures (see Paragraph 0020 of the published specification). The parameters of the applied electromagnetic radiation are so selected to produce no permanent or visible skin damage and so that the incidence or likelihood of skin damage from exposure to UV or X-ray radiation is reduced. Applicant's prophylactic radiation may be applied before, during or after the exposure to potentially damaging UV or X-ray radiation (but should be applied within a predetermined interval of the potentially dangerous exposure).

Applicant's method avoids permanently damaging the target skin structures. This is in stark contrast to prior art techniques which necessarily permanently damage skin structures in order to heal tissue that already has undesirable visible conditions.

The Prior Art The Menezes article, the main reference relied on by the Examiner in rejecting the elected claims discloses a method for preventing ultraviolet radiation from killing fibroblasts. Menezes method consists of subjecting naked fibroblasts to as many as three half-hour doses of incoherent infrared radiation spanning the spectral range of at least 700 nm to 1000 nm and optionally including frequencies in the continuum from 1000 nm to 2000 nm. Successive half-hour doses are separated by a three-hour interval. During the radiation, the fibroblasts are cooled to 20-25°C (68-77°F). After the exposure of the fibroblasts to one, two or three half-hour doses of infrared continuous spectrum radiation, the fibroblasts are washed and the medium is exchanged, all over a 20 minute period, and then the fibroblasts are exposed, without a cooling bath, to UV radiation.

The Menezes method does not include several features of applicant's invention, for which applicant presents separate independent claims herein. Each of the independent claims 109, 110, 113, 115, 117, and 118 includes all of the limitations of amended claim 68 except for the pulse duration limitation. Claim 112 recites that the application of electromagnetic radiation is limited to *during or after* exposure to dangerous Xray or UV. In claim 116, the reference to ultraviolet radiation has been eliminated, so that claim 116 refers only to protective treatment for Xray damage (radiation dermatitis and not sunburns and poikiloderma).

Claim 68 Claim 68 is amended herein to recite that the applying of the electromagnetic radiation to the skin surface increases the local temperature in skin structures including blood vessel cell walls and keratinocytes in the skin to stimulate a healing response and a release of growth factors and other tissue substances, without permanently damaging the skin structures. This language (from Paragraph 0020 of the published specification) distinguishes over

mainstream uses of electromagnetic radiation to treat damaged skin. It is well known that those treatment methods necessarily damage skin structures to repair or reverse the skin damage. As set forth in *Lasers in Cutaneous and Aesthetic Surgery*, Editors Kenneth A. Arndt et al., Lippincott-Raven Publishers, 1997, page 32, there is a “sequency of light-heat-ruin that occurs at microscopic sites, such as pigmented cells, and tattoo ink particles, which selectively absorb light pulses.... Thermal coagulation or thermally mediated mechanical damage, or both, are involved, depending on the rate of energy deposition in the targets.” The same reference text on page 37 states that “[s]elective photothermolysis makes use of a variety of thermally mediated damage mechanisms, including thermal denaturation, mechanical damage resulting from rapid thermal denaturation, mechanical damage resulting from rapid thermal expansion or phase changes (cavitation) , and pyrolysis (changes in the primary chemical structure).” Assuming that selective damage to dermal structures is desirable for treatment purposes, the article “Selective Thermal Effects with Pulsed Irradiation from lasers: from Organelle to Organelle,” JA Parrish et al., *Invest Dermatol.*, 1983 Jun 80 Suppl: 75s-80s, teaches that specific damage by selectively absorbed pulsed lasers can be predicted and controlled by adjusting the wavelength and pulse duration. Similarly, the article “Selective Photothermolysis: Precise Microsurgery by Selective Absorption of Pulsed Radiation,” RR Anderson et al., *Science*, 1983 April 29 220 (4596): 524-7, observes in its abstract that “suitably brief pulses of selective absorbed optical radiation can cause selective damage to pigmented structures, cells and organelles in vivo.” (Copies of selected excerpts appended hereto as Exhibit A.)

Claim 68 is further amended herein to recite that applicant’s method applies pulses of electromagnetic radiation to a skin surface of an individual to at least reduce the incidence or likelihood of short-term or long-term non-cancerous visible damage to the skin including ***radiation dermatitis, sunburns, and poikiloderma*** caused by exposure of the individual to Xray or ultraviolet radiation. None of the prior art currently relied on by the Examiner particularly

Menezes et al. either discloses or suggests a method that reduces the incidence or likelihood of *radiation dermatitis, sunburn or poikiloderma*.

Claim 68 is also amended herein to more particularly define that the electromagnetic radiation is applied in pulses and that the pulses of electromagnetic radiation are characterized by parameters including pulse duration of less than about 2 seconds.

Given that Menezes teaches the application of *half-hour* doses of radiation, it would hardly be obvious to one of ordinary skill in the art, following the teachings of Menezes, to apply pulses of electromagnetic radiation of *2-seconds or less duration* to a skin surface to reduce, if not eliminate, the incidence or likelihood that those skin surfaces will be damaged by exposure to a source of Xray or ultraviolet radiation.

Other references, previously cited by the Examiner in the present application, and teaching the application of electromagnetic radiation in pulses of short duration would not suggest to one of ordinary skill in the art to modify the approach of Menezes to apply pulses of electromagnetic radiation of *2-seconds or less duration*. Those other references are directed to different end results (e.g., hair, wrinkle or varicose-vein removal). Moreover, Menezes is interested in duplicating the effects of the natural world where people in the sun are exposed to infrared radiation during morning hours and subsequently receive peak doses of solar UV. Two seconds is just too short a time to duplicate the effects of the natural world as observed by Menezes et al.

Claim 73 has been amended like claim 68 and distinguishes over Menezes for the reasons presented hereinabove with reference to claim 68.

Claim 109 New claim 109 incorporates all of the limitations of current claim 68 except for the pulse duration limitation and additionally recites that the electromagnetic radiation is broadband radiation including visible wavelengths as well as infrared wavelengths, between 400 nm and 1200 nm.

Applicant discloses such broadband energy application in Paragraphs 0024 and 0039 of the published application.

The Menezes method is particularly limited to infrared radiation between 700 nm and 2000 nm. The discussion in the reference is quite clear that it is infrared radiation alone that has the desired effect.

It would not occur to one of ordinary skill in the art to apply wavelengths between 400 nm and 700 nm in the method of Menezes.

Claim 110 New claim 110 incorporates all of the limitations of prior or unamended claim 68 and additionally recites that the electromagnetic radiation includes one or more single or isolated wavelengths.

Applicant discloses such single or isolated wavelengths in Paragraphs 0054 of the published application.

Clearly, in the method of Menezes et al., one must apply infrared radiation in a continuous spectrum. There is no suggestion of using single or isolated wavelengths. Moreover, using single or isolated wavelengths contradicts the reasoning of the Menezes paper that “interactions between different wavelengths” (p. 632) in the infrared portion of sunlight (broad spectrum, not laser frequencies) is responsible for natural protection against the ill effects of UV (particularly fibroblast toxicity).

One of ordinary skill in the art would not consider the application of single or isolated wavelengths of radiation in the method of Menezes.

Claim 112 New claim 112 incorporates all of the limitations of current claim 68 except for the pulse duration limitation and except that the application of electromagnetic radiation is limited to *during or after* exposure to ultraviolet radiation.

One of ordinary skill in the art, attempting to follow the teachings of Menezes, would administer the IR radiation *only prior* to exposure to UV light. In the method of Menezes, if the

fibroblast cells are not properly treated *prior to* exposure to UV, the cells *die*. Clearly, treatment during or after exposure to UV would not be beneficial. One would not bother to treat fibroblasts with infrared radiation *during or after* exposure to UV. It would be too late.

Claim 113 New claim 113 incorporates all of the limitations of current claim 68 except for the pulse duration limitation and adds the further limitation of providing an exogenous chromophore in tissues along the skin surface prior to the applying of the electromagnetic radiation to the skin surface in at least one treatment session.

In this regard, applicant traverses the rejection of dependent claim 95 and maintains that the application of an external chromophore is contraindicated in the Menezes method.

According to the teachings of Menezes et al., it is necessary for multiple wavelengths of infrared radiation to be absorbed by the fibroblasts to achieve the desired protection against UV toxicity. Menezes et al teach that the multiple wavelengths interact or cause interactions in the cells to provide the desired protection. Also, in column 2, page 632, Menezes et al. explain that “the protection here described is a constitutive mechanism of cellular protection, mediated by molecules existing in small amounts in the cells, with further induction by IR.” An exogenous chromophore at best would contribute nothing to the cellular protection mechanism and at worst could possibly block transmission of a necessary wavelength into the fibroblasts. Therefore, one of ordinary skill in the art would be loathe to provide an exogenous chromophore in the method of Menezes et al. In addition, an external chromophore would absorb the treatment radiation and generate heat, which would either interfere with the Menezes cooling of the fibroblasts or would be absorbed by the cooling bath. Thus, one of ordinary skill in the art would be motivated not to provide an exogenous chromophore in the Menezes method.

Claim 115 New claim 115 incorporates all of the limitations of current claim 68 except for the pulse duration limitation and additionally recites transmitting an additional form of wave energy into biological tissues along the skin surface prior to, during or after the applying of

the electromagnetic radiation to the skin surface, the additional form of wave energy being taken from the group consisting of mechanical wave energy and magnetic field wave energy.

Applicant discloses such ancillary waveform energy application in Paragraphs 0046 and 0047 of the published application.

The Menezes method shows that broadband infrared radiation alone is sufficient to protect fibroblast cells from the cytotoxic effects of UV radiation. (“[T]hree IR irradiations abolished the cytotoxicity of this dose of UVA completely....” Page 631, col. 1, 3rd Para.) Not only does the Menezes article say nothing about ancillary forms of waveforms energy but such ancillary waveforms would be superfluous, in the mind of the ordinarily skilled artisan, given the 100% protection to fibroblasts afforded by the Menezes method..

It would not occur to one of ordinary skill in the art to apply mechanical wave energy and/or magnetic field wave energy in the method of Menezes et al.

Claim 116 New claim 116 incorporates all of the limitations of prior or unamended claim 68 except for the pulse duration limitation and except that the application of electromagnetic radiation is limited to protecting the skin from damage owing to Xray radiation.

The Menezes method is directed solely to protecting against cytotoxic effects of UV radiation. Nothing in the Menezes article suggests protecting skin from damage arising from Xrays.

Claim 117 New claim 117 incorporates all of the limitations of current claim 68 except for the pulse duration limitation and additionally recites that the applied electromagnetic radiation is absorbed by melanin in the epidermis and hemoglobin in the capillaries and blood vessels of the dermis, increasing heat of melanin, blood vessel walls, keratinocytes, collagen and Langerhans cells, to promote healing, collagen synthesis and remodeling and reduce the likelihood of occurrence of at least one kind of potential non-cancerous visible skin damage taken from the group consisting of radiation burns, sunburns, chronic redness, chronic scaling

and dry skin, hypopigmentation, hyperpigmentation, atrophy, thinning, edema, swelling, fine blood vessel prominence, wrinkles and scarring.

Support for claim 117 is found throughout applicant's specification including Paragraphs 0002, 0020 and 0165 of the published application. Applicant is prepared to amend the specification to include antecedent support for the well-known characteristics of radiation dermatitis and poikiloderma, if required. As indicated above, the well-known characteristics are available from standard treatises or texts in the field of dermatology.

Claim 117 is patentable over the Menezes publication inasmuch as that reference is directed solely to protecting against cytotoxic effects of UV radiation on fibroblasts. Nothing in the Menezes article suggests applying electromagnetic radiation for absorption by melanin in the epidermis and hemoglobin in the capillaries and blood vessels of the dermis, increasing heat of melanin, blood vessel walls, keratinocytes, collagen and Langerhans cells, to promote healing, collagen synthesis and remodeling and reduce the likelihood of occurrence of at least one kind of potential visible skin damage taken from the group consisting of radiation burns, sunburns, chronic redness, chronic scaling and dry skin, hypopigmentation, hyperpigmentation, atrophy, thinning, edema, swelling, fine blood vessel prominence, wrinkles and scarring.

Claim 118 New claim 118 incorporates all of the limitations of current claim 68 except for the pulse duration limitation and additionally recites that the applied electromagnetic radiation has wavelengths limited to a band taken from the group consisting of between 400 nm and 550 nm and between 700 nm and 900 nm.

Support for claim 118 is found in Paragraphs 0067 and 0152 of applicant's published application.

Claim 118 is patentable over the Menezes publication inasmuch as that reference is directed solely to a method where applied electromagnetic radiation includes the entire infrared band extending from 700 nm to 2000 nm. Menezes et al. make it clear that the entire spectrum

from 700 nm to 2000 nm is likely needed to enable the salutary effects, presumably attributable to the synergistic interaction within the fibroblasts of many different wavelengths. (Menzes et al. point out that the salutary effects are probably due to wavelengths between 700 and 1000 nm.) One of ordinary skill in the art would not limit the applied spectrum to the band from 700 nm to 900 nm and certainly would not limit the band to visible light (between 400 nm and 700 nm).

Dependent claims not specifically argued herein are patentable in part because their respective independent claims are patentable. Concomitantly, the rejections of the dependent claims are moot in view of the amendments and arguments presented herein.

Dependent claim 86 has been amended to clarify what applicant meant to claim by “indirect exposure” of a skin surface to Xray or ultraviolet radiation. Claim 86 is directed the prophylactic treatment of skin areas that do not themselves receive the damaging radiation but instead are affected indirectly, for instance, through chemicals diffusing from radiated skin areas. As set forth in Paragraphs 0031 and 0032 of the published application, “the present invention contemplates in part the treatment of skin areas that are not exposed directly to the sun or other source of Xray or UV radiation. Accordingly, skin surfaces that are covered by clothing during an individual's exposure to the sun may be subject to the light treatment of the present invention. Such treatment is based on the fact that melanomas are known to occur in non-exposed areas of an individual's skin. The mechanism for this is not known and may possibly rest on a blood factor.”

Conclusion

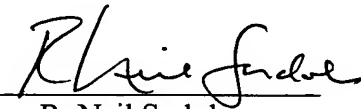
For the foregoing reasons, independent claims 68, 73, 109, 110, 112, and 113-118, as well as the claims dependent therefrom, are deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

The claim amendments, if any, made herein are made without prejudice to applicants' right to pursue additional subject matter in a separate continuation or divisional application.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

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Dated: 1 July 2008